

STATEMENT IN OPPOSITION TO MICHIGAN HOUSE BILL 5223

submitted by

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Chairman Vuapel and members of the committee - thank you for the opportunity to speak before you on HB 5223, a bill concerning drug price transparency.

My name is Dr. Stephen Rapundalo. I am President and CEO of MichBio, the Michigan Biosciences Industry Association. Our organization is comprised of 200 members and represents the interests of the large and small biopharmaceutical companies developing medicines for curing and treating many of the most complex and life-threatening diseases. In total, there are >8800 direct jobs in Michigan's biopharma sector with a total employment impact of about 100,000 yielding >\$18 billion in economic output.

By background, I spent almost 20 years in the pharmaceutical industry developing new therapies for heart disease, everything from small molecule drugs, most notably Lipitor, to complex biologics. I have a strong understanding of pharmaceutical research and development and the arduous process and cost to get a new drug to market.

MichBio and its biopharma members share the concerns about the affordability of prescription drugs and cost of health care. However, we're alarmed that HB 5223 will harm our ability to afford the costly and time-consuming process of bringing new therapies to market.

HB 5223 would require biopharmaceutical companies to publicly disclose all sorts of proprietary, competition-sensitive and confidential information about a drug's research-to-market expenses.

On its face, this may seem like a simple and straightforward solution to address drug costs. However, the legislation assumes that a "reasonable" price for a particular drug could be determined if consumers better understood the costs associated with developing, manufacturing, marketing and selling that drug. In reality, there is no direct line to follow from such expenses to the patient's out-of-pocket costs.

The proposed reporting requirements would be especially burdensome on the engine of biotech innovation — the biotech startups and emerging companies. Indeed, the majority of Michigan's biopharmaceutical sector consists of pre-revenue companies with less than 50 employees whose drug candidates have yet to reach the market. It's taken the last 15-20

years for Michigan's biopharma sector to grow into a viable bioscience innovation cluster.

These companies must use their limited resources as efficiently as possible to speed the discovery of treatments that can improve the lives of patients, and to reinvest in future innovation. Reporting requirements contained in this proposal will divert scarce resources to accounting and compliance activities that could be better used on developing therapies that patients need.

Moreover, as written, HB 5223 unfairly focuses only on the costs associated with a single drug. In reality, pharmaceutical companies often maintain a portfolio of R&D initiatives that are intertwined. It's not that simple to track a single drug candidate's costs through the R&D process within a single company. This is so because of the often amorphous nature of development expenses, and the difficulty in assigning concrete scientific credit for the innovation associated with a drug's approval to various failures or insights gained from other research and disease areas. The determination becomes even more complicated when you consider partnerships, acquisitions and other third-party relationships that are often covered by confidentiality agreements.

HB 5223 threatens the entire biopharma industry in Michigan. The only way small research-intensive companies survive is because investors are willing to take huge risks and put significant financial resources behind our ideas. This risk-taking is based on the expectation that successful research endeavors will more than pay for all the failures that occurred along the way. Investors, including large pharma, will be reluctant to fund small companies hampered by burdensome and costly regulations. Existing companies will leave Michigan and/or technologies discovered here will be commercialized in more business-friendly regions. That would mean high-wage job losses and lower economic output.

The Michigan bio-industry is an interconnected system that includes emerging, small and large biopharmaceutical companies, as well as academic and clinical research institutions and investors. The state survived significant consolidation in the biopharma sector over the last 15 years. Furthermore, the industry's growth continues to be stifled by a lack of business-friendly policies, making us less competitive than other regions trying to grow robust bioscience clusters. Schemes to attack the last growing, innovative industry would be additionally counterproductive for both job creation and economy.

The biopharma industry welcomes an honest dialogue about the drug prices in the greater context of our total health care system. Our shared goal should be to design an economically sustainable system that ensures patient access and promotes biomedical innovation.

Unfortunately, HB 5223 will do nothing to promote this dialogue, nor will it help patients better understand their drug costs. It will serve only to add more risk to our already perilous business model and dampen the attractiveness of investing in Michigan's biopharmaceutical companies.

For all the above reasons, MichBio and its members, stand opposed to HB 5223.